

identifying particular stem cells of interest, after those cells have been sorted based upon non-expression of  $\beta_2m$ .

On September 19, 2002, in the first communication in this case, the Examiner required the Applicant to elect a specific species of stem cell marker. The Examiner stated that "*each of [the] markers can represent different cell types and are not markers that are representative of only stem cells.*" The Examiner included in the list of species, "*genes that encode the major histocompatibility complex.*"

The Applicants respectfully point out that genes that encode the major histocompatibility complex ("MHC") are not the stem cell markers contemplated by the Applicants' invention, as claimed. Rather, as described throughout the specification (e.g., at Page 6, lines 24-25) and in the claims (e.g., claims 8 and 25), proteins expressed by genes that encode the MHC may be included among stem cell markers. The Applicants therefore presume that this first enumerated species is, in fact, directed to such proteins. As such, the Applicants respectfully elect this first enumerated species for further prosecution on the merits pursuant to 35 U.S.C. § 121. The Applicants further respectfully assert that each of claims 1-42 is readable upon this elected species.

The foregoing election notwithstanding, the Applicants respectfully traverse the restriction requirement, and respectfully submit that the restriction requirement is improper. The Examiner cites to 35 U.S.C. § 121 as the basis for the restriction requirement; yet that section permits restriction only when a) inventions are independent or distinct, and b) there is a serious burden on the Examiner. MPEP § 803. Restriction is not proper where a claim does not recite independent or distinct

inventions.

The Applicants recognize that the stem cell markers of their invention may, in various instances, be associated with cells that are not stem cells. However, the identification of stem cells by the methods of the present invention is not accomplished simply by searching for cells that express one of the aforementioned markers. Rather, as described in each independent claim of the present invention, cells are first sorted based upon expression of  $\beta_2m$ . Once cells are identified as not expressing  $\beta_2m$ , particular stem cells may thereafter be conveniently identified using known stem cell markers. Independent inventions are not predicated upon the selection among these markers.

The Applicants respectfully submit that the Examiner may examine the entire original application as filed, consistent with 35 U.S.C. § 121, without any serious burden. Each of the species is closely related: they are each a stem cell marker limited to the single application of identification of stem cells from a sample of cells that do not express  $\beta_2m$ . On this ground, the Applicants respectfully request that the Examiner withdraw the restriction requirement with respect to the markers recited in the claims.

To the extent the Examiner requires restriction of the claims to a single stem cell marker, the Applicants respectfully draw the Examiner's attention to 37 C.F.R. § 1.141, which permits a reasonable number of species claims, even if they are directed to independent and distinct inventions, if such claims depend from an allowable generic claim, of which the Examiner has identified three (i.e., claims 1, 5 and 21). The Applicants respectfully submit that it is improper to require restriction with respect to the various stem cell markers on the grounds they are each an independent

and distinct invention, for the reasons set forth in § 1.141. The Applicants further respectfully submit that, in any event, the Examiner may make a search of the art for the use of stem cell markers with respect to cells that do not express  $\beta_2m$  without any serious burden.

For the foregoing reasons, the Applicants respectfully request that the Examiner withdraw the restriction requirement, and respectfully requests further, favorable action on the merits.

Respectfully submitted,

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